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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,641	Applicant(s) HAVERKOST ET AL.	
	Examiner Sarah K. Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-51 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-16, 18-29, 34-46 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10, 11, 17, 30, 31, 33, 47 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1,3-8,10,11,17,30,32,47, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,201,757 (Heyn et al) in view of US Patent No. 6,042,589 (Marianne).

Heyn discloses a stent introducer (Figures 2 and 4) that includes a shaft (78) with a distal tip (84), inner sheath (100), stent (106), anterograde sheath (82) attached to the distal tip (84), and a retrograde sheath (94). The anterograde sheath (30) and the retrograde sheath (20) are moveable between the positions of abutting one another and being laterally spaced from one another. The anterograde sheath (30) is axially moveable in a distal direction by distally moving the shaft (44), since the sheath (30) is connected to the shaft (44) by way of distal tip (40) (column 5, lines 30-35 and column 6, lines 27-29). Heyn also includes an anchoring means in the form of detent (104) in the retrograde portion for preventing axial movement of the stent. Regarding claims 10 and 11, a "radial spacer" attached proximal to the distal tip provides space between the inner sheath (100) and the anterograde sheath (82).

The claims require a means for anchoring the stent after expansion of the proximal end and for minimizing relative movement between the proximal end of the stent and the body lumen. Applicant's specification discloses that an acceptable "anchoring means" is a balloon positioned the retrograde portion (page 3, line 28- page 4, line 2).

Heyn includes all the limitations of the claimed invention, but fails to form the anchoring means as a balloon. Marianne discloses a stent (7) introducer with a retracting sheath (16) and a proximal anchoring means in the form of a balloon (20). Similar to the anchor (104) of Heyn, the balloon prevents axial movement of the stent during retraction of the sheath for deployment (column 3, lines 5-8). In this way, the detent of Heyn and the balloon of Marianne are functionally equivalent. Marianne teaches that this type of balloon, positioned in the retrograde portion of the stent, also allows the stent to be withdrawn and replaced in a more suitable position if necessary and can be used as a dilation balloon (column 3, lines 5-55). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide the user with the added capabilities of repositioning the stent and dilating the vessel without changing catheters.

As shown in Figure 4, the balloon (20) of Marianne is capable of performing the functions of anchoring the proximal end of the stent after expansion and minimizing relative movement between the proximal end of the stent and the body lumen because it can be inflated to the diameter of the body lumen.

Marianne further teaches that an inner sheath mounted over the shaft (8) can define an inflation lumen (22) for the balloon (20) (column 4, line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Marianne to adapt the inner sheath of Heyn to define an inflation lumen for the balloon of the device, as modified above.

Regarding claims 7, 8, and 17: The modified Heyn device fails to include a medial sheath. In Figure 13 of Heyn, a medial sheath (246) is located between the

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inner and retrograde sheaths. It terminates proximally to the stent. Heyn teaches that such a "medial sheath" (246) can be provided as a proximal stop for the stent (column 11, line 27) so that it won't travel into the proximal region of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a medial sheath in the modified Heyn device in order to prevent the stent from traveling proximally into the device.

2. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of Marianne, as applied to claim 30 above, and further in view of US Patent No. 5,445,646 (Euteneuer).

Heyn, as modified by Marianne above, includes all the limitations of claims 31 and 33, except for making the anterograde sheath cover more of the stent than the retrograde sheath and overlapping the two sheaths. Euteneuer discloses a stent introducer in Figure 2 that is similar to Heyn. The device includes both a retrograde (14) and an anterograde (16) sheath. The anterograde sheath covers a greater portion of the stent than the retrograde sheath in order to provide an overlapping region. Euteneuer explains that the overlap forms a seal (column 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to lengthen the anterograde sheath of the modified Heyn device so that it overlaps the retrograde sheath, as Euteneuer teaches that this structure forms a seal around the stent.

Response to Arguments

3. Applicant's arguments filed 8/28/06 have been fully considered but they are not persuasive. Applicant argues that the modified Heyn device does not perform the functions of *"anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration"* and *"minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end."* These limitations are directed toward the intended use of the device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant's specification discloses that an acceptable "anchoring means" is a balloon positioned the retrograde portion (page 3, line 28- page 4, line 2). As shown in Figure 4 of Marianne, the balloon (20) is capable of performing the functions of anchoring the proximal end of the stent after expansion and minimizing relative movement between the proximal end of the stent and the body lumen because it can be inflated to the diameter of the body lumen to engage the expanded stent.

Applicant's arguments fail to particularly point out structural deficiencies of the prior art, but merely allege that the modified device does not perform as set forth in the claims. Since the claims are directed toward an article of manufacture, the prior art need only disclose the structural components of the claims that are capable of performing the intended functions. Heyn and Marianne are not required to state that the device performs to anchor the stent proximal end after expansion of the proximal

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end into the expanded configuration and minimize relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end. As discussed above, the modified Heyn device is capable of performing these functions.

Further, applicant's specification points out a different method of deploying the device. Page 5, lines 25-28 states, *"In the alternative, the balloon may be inflated to anchor the proximal end of the endoluminal device against the retrograde sheath, in which case the retrograde sheath is not retracted until after deflating the balloon after the antegrade portion of the endoluminal device has been deployed."* This is very similar to the deployment method of Marianne recited in column 3, lines 5-13. If applicant's balloon also performs similarly to the Marianne balloon, then isn't Marianne also capable of performing similarly to applicant?

4. Applicant also argues that there is no motivation to combine Heyn and Marianne. Both Heyn and Marianne disclose stent delivery devices with anchors that prevent axial movement of the stent during retraction of the sheath, so they are considered to be analogous to one another. Since the detent (104) of Heyn and the balloon (20) of Marianne prevent axial movement of a stent during deployment, these components are functionally equivalent. Marianne provides proper motivation for substituting the balloon for the detent in the Heyn device by teaching that this type of balloon allows the stent to be repositioned and can be used as a dilation balloon (column 3, lines 5-55). Therefore, the combination of Heyn and Marianne is considered to be proper and meet all of the structural requirements of the claimed invention.

5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

6. Applicant's arguments with respect to the rejection of claims 31 and 33 have been considered but are moot in view of the new ground(s) of rejection. The previous omission of Marianne from this 103 rejection was in error, because claims 31 and 33 depend from claim 30, which is rejected under the combination of Heyn and Marianne.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SKW

11/7/06

SKW
Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER